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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,521

06/24/2005

Hiroataka Haro

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23373 7590 12/16/2008  
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EXAMINER

ZAREK, PAUL E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

12/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/540,521	HARO, HIROTAKA	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claim 5 has been amended and Claims 6-8 have been cancelled by the Applicant in correspondence filed on 10/30/2008. Claim 5 is currently pending. This is the second Office Action on the merits of the claim(s).

### ***Priority***

2. Applicant's claim for the benefit of a prior-filed international application JP03/16580 (filed on 12/24/2003) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 12/24/2003.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The foreign priority documents JP2002-373527 and JP2003-187675 (filed on 12/25/2002 and 06/30/2003, respectively) have been received. The priority date of the instant application is 12/25/2002.

### ***Response to Arguments***

4. Applicant's response filed on 10/30/2008 to the Non-Final rejection mailed on 06/30/2008 is acknowledged herewith.

5. In view of Applicant's cancellation of Claims 6-8, the objections, and rejection under 35 U.S.C. §§ 102, 103, and 112 to Claims 6-8 are withdrawn. In view of Applicant's amendment of Claim 5, the rejection of Claim 5 under 35 U.S.C § 112 is withdrawn.

6. Amended Claim 5 is examined on its merits and the following **FINAL** rejection is made.

***Claim Rejections - 35 USC § 103***

7. The text of 35 U.S.C. § 103 can be found in a prior Office action.
8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haro, et al. (Spine, 1997, already of record) in view of Haro, et al. (Journal of Spinal Disorders, 1999, already of record).
9. Amended Claim 5 is drawn to a method of treating a herniated disc or herniated nucleus pulposus (HNP) characterized by directly administering an active ingredient comprising MMP-7 to the affected site of the herniated disc or HNP.
10. Haro, et al. (Spine), teach the treatment of herniated nucleus pulposus with human stromelysin-1 (MMP3). Both *in vitro* and *in vivo*, Haro, et al. (Spine), demonstrate that MMP-3, injected into the murine nucleus pulposus tissue, rapidly reduced the size of the herniated disc. Haro, et al. (Spine) do not teach the use of MMP-7 to treat a herniated disc or HNP.
11. Haro, et al. (J. Spinal Disorders), teach that MMP-7 could reduce the size of HNP in tissues. “Human MMP-3 is capable of reducing the size of HNP tissues in both *in vitro* and *in vivo* experiments. Recombinant MMP-7 and MMP-8 may also have such abilities based on substrate specificity.” (pg 248, col 1, paragraph 2).
12. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the method of Haro, et al. (Spine), with the teaching of Haro, et al. (J. Spinal Disorders), to administer MMP-7 directly to the area affected by a herniated disc or HNP.

*Conclusion*

13. No claims are allowed.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/  
Primary Examiner, Art Unit 1625